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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,054	04/19/2004	David R. Elmaleh	910000-2042.1	2370

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,054	ELMALEH ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-146* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17,32-43,118,119,122 and 123 are drawn to a radioactively labeled analog of a fatty acid, classified in class 424, subclass 1.85.

II. Claims 18-31,120 and 121 are drawn to radioactively labeled analog of a fatty acid, classified in class 424, subclass 1.85.

III. Claims 44-54,124 and 125 are drawn to radioactively labeled analog of a fatty acid, classified in class 424, subclass 1.85.

IV. Claims 55-65,126 and 127 are drawn to radioactively labeled analog of a fatty acid, classified in class 424, subclass 1.85.

V. Claims 66-77,128 and 129 are drawn to radioactively labeled analog of a fatty acid, classified in class 424, subclass 1.85.

VI. Claims 78-97 and 142-146 are drawn to a method of measuring blood flow in a subject, classified in class 424, subclass 9.1.

VII. Claims 98-117 are drawn to a method of measuring metabolism in a subject, classified in class 424, subclass 9.1.

VIII. Claims 130-141 are drawn to a method of synthesizing a fatty acid, classified in class 424, subclass 1.11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II,III,IV,V are directed to related radioactively labeled analog of a fatty acid. The related inventions are distinct if the (1) the inventions as claimed are

either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed contain a radioactive halogen isotope that is used for medical diagnosis. The fatty acid backbone chain and substituents of this backbone chain are different. Each compound will have different physical and chemical properties, such as reactivity. Also, depending on the substituents and radioactive isotopes utilized they will have different toxicities, site specificities, uptake and excretion factors which means that they will have different modes of function and effect. The synthesis of each compound will involve different reaction steps since the substituents disclosed are very different, such as cyclopropyl, cyclobutyl, aryl, heterocyclic organic. The synthesis of different cyclic ring substituents are not the same whereas some rings, such as cyclobutyl ring subsituents are much more difficult to generate. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each compound would require a separate search and create a burden of search for the office.

3. Inventions II and III,IV,V are directed to related radioactively labeled analog of a fatty acid. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See

MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions as claimed contain a radioactive halogen isotope that is used for medical diagnosis. The fatty acid backbone chain and substituents of this backbone chain are different. Each compound will have different physical and chemical properties, such as reactivity. Also, depending on the substituents and radioactive isotopes utilized they will have different toxicities, site specificities, uptake and excretion factors which means that they will have different modes of function and effect. The synthesis of each compound will involve different reaction steps since the substituents disclosed are very different, such as cyclopropyl, cyclobutyl, aryl, heterocyclic organic. The synthesis of different cyclic ring substituents are not the same whereas some rings, such as cyclobutyl ring subsituents are much more difficult to generate. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each compound would require a separate search and create a burden of search for the office.

4. Inventions III and IV,V are directed to related radioactively labeled analog of a fatty acid. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions as claimed contain a radioactive halogen isotope that is used for medical diagnosis. The fatty acid backbone chain and substituents of this backbone chain are different. Each

compound will have different physical and chemical properties, such as reactivity. Also, depending on the substituents and radioactive isotopes utilized they will have different toxicities, site specificities, uptake and excretion factors which means that they will have different modes of function and effect. The synthesis of each compound will involve different reaction steps since the substituents disclosed are very different, such as cyclopropyl, cyclobutyl, aryl, heterocyclic organic. The synthesis of different cyclic ring substituents are not the same whereas some rings, such as cyclobutyl ring subsituents are much more difficult to generate. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each compound would require a separate search and create a burden of search for the office.

5. Inventions IV and V are directed to related radioactively labeled analog of a fatty acid. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions as claimed contain a radioactive halogen isotope that is used for medical diagnosis. The fatty acid backbone chain and substituents of this backbone chain are different. Each compound will have different physical and chemical properties, such as reactivity. Also, depending on the substituents and radioactive isotopes utilized they will have different toxicities, site specificities, uptake and excretion factors which means that they will have different

modes of function and effect. The synthesis of each compound will involve different reaction steps since the substituents disclosed are very different, such as cyclopropyl, cyclobutyl, aryl, heterocyclic organic. The synthesis of different cyclic ring substituents are not the same whereas some rings, such as cyclobutyl ring subsituents are much more difficult to generate. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each compound would require a separate search and create a burden of search for the office.

6. Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of measuring blood flow, for example perfusion can be accomplished via ultrasound and gas filled liposomal microbubbles. It is not necessary to utilize radioactively labeled analogs of a fatty acid.

7. Inventions I-V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method

of measuring metabolism in a subject can be accomplished by administering a psychoactive compound to measure cerebral metabolism via PET.

8. Inventions I-V and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of synthesizing the compounds of the instant claims can be accomplished using different reaction schemes. Each compound is unique and would require specific reactions in a specific order to generate the required substitution.

9. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the method of measuring blood flow and the method of measuring metabolism in a subject. Each method can utilize different compounds and techniques, see above.

10. Inventions VI,VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the method of measuring blood flow, the method of measuring metabolism in a subject and the method of synthesizing a compound of the instant claim 1. As shown above the methods of measuring blood flow and metabolism

do not necessarily require the compounds of the instant claims so the method for synthesizing such compounds is unrelated.

11. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) **an election of an invention** to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

12. This application contains claims directed to the following patentably distinct species:

13. Group I: a.) n, m, R and Z. b.) Heart, liver or tumor tissue. c.) radioactive isotopes. d.) depending on the choice of Z; cyclic alkane, i.e. cyclopropyl, etc. or heterocyclic organic substituent, i.e. 3-5 membered ring, etc. e.) please choose between the organic substituent reducing metabolic hydroxylation or dehydrogenation. If appropriate, choose the corresponding A,x,m,n,R,cis/trans and R,R or S,S.

14. Group II: a.) n,m,D and E. b.) Heart, liver or tumor tissue. c.) radioactive isotopes. d.) aryl group, i.e. 3-5 membered ring, etc. e.) please choose between the organic substituent reducing metabolic hydroxylation or dehydrogenation.

15. Group III: a.) A,y,m,n,p,R,X,cis/trans and R,R or S,S. b.) Heart, liver or tumor tissue. c.) radioactive isotope. d.) please choose between the organic substituent reducing metabolic hydroxylation or dehydrogenation.

16. Group IV: a.) X,Y,A,Z,m,n,p and R. b.) Heart, liver or tumor tissue. c.) aryl group, i.e. 3-5 membered ring, etc. d.) please choose between the organic substituent reducing metabolic hydroxylation or dehydrogenation.

17. Group V: a.) A,y,m,n,p,R and X. b.) Heart, liver or tumor tissue. c.) aryl group, i.e. 3-5 membered ring, etc. d.) please choose between the organic substituent reducing metabolic hydroxylation or dehydrogenation.

18. Group VI: a.) second radioactive tracer. b.) disease, i.e. myocarditis, colorectal, diabetes, etc. c.) tissue, i.e. brain, liver, etc. and type of tissue, i.e. normal, diseased,

etc. d.) the step of retaining the composition, i.e. by reducing transport, by reducing dehydrogenation, by reducing hydroxylation, etc.

19. Group VII: a.) second radioactive tracer. b.) disease, i.e. myocarditis, colorectal, diabetes, etc. c.) tissue, i.e. brain, liver, etc. and type of tissue, i.e. normal, diseased, etc.

20. Group VIII: a.) cyclic alkane, i.e. cyclopropyl, etc. b.) heterocyclic organic substituent, i.e. 3-5 membered ring, etc. c.) radioactive isotope.

21. Please choose one of each species listed accordingly in relation to the elected group. **For example**, if electing group I please choose one of each n, m, R and Z, one of the types of tissue, one radioactive isotope, one Z group (if choosing a heterocyclic organic substituent please choose the ring size) and whether the organic substituent reduces transport by dehydrogenation or hydroxylation.

22. The species are independent or distinct because each compound (species) will have different physical and chemical properties, such as reactivity. Also, depending on the substituents and radioactive isotopes utilized they will have different toxicities, site specificities, uptake and excretion factors which means that they will have different modes of function and effect. Each different second radiotracer is only going to increase the differences in these factors.

23. The differences in the disease to be monitored, such as myocarditis (inflammation due to infection) or ischemia could occur in different tissues of the heart and may be monitored at different time intervals. The differences in the tissue (brain,

liver, bone, etc.) to be monitored would require different administration techniques and amounts of compound as well as different monitoring time intervals.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-146 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

24. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
September 14, 2006

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER